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HAHN LOESER & PARKS, LLP
One GOJO Plaza
Suite 300
AKRON, OH 44311-1076

EXAMINER	
HIGGINS, GERARD T	

ART UNIT	PAPER NUMBER
1785	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
akron-docket@hotmail.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,593	MOMMA ET AL.	
	Examiner	Art Unit	
	GERARD T. HIGGINS	1785	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,11,12 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,11,12 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2010* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 04/28/2010 has been entered. Currently claims 1-6, 9, 11, 12, and 20-24 are pending, claims 7, 8, 10, and 13-19 are cancelled, and claims 21-24 are new.

Drawings

2. The drawings were received on 04/28/2010. These drawings are unacceptable because the replacement sheet has annotations and the annotated sheet is the clean sheet.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **24** see [0023]. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be

notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 2 is objected to because of the following informalities:

The phrase "other than the comparatively radiopaque material together" is objected to grammatically. This objection will be removed if the limitation is changed to "other than the comparatively radiopaque material, and together" which is how the claim will be interpreted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claim 24, the Examiner does not find support for the limitations of this claim for various reasons. This claim is not supported because the concept of having the marker element form an end portion is a separate concept from the welding of the at least one marker element to at least one leg of a leg ring recited in claim 23. The end portions are not welded to a leg of a leg ring because the entire end portion is

formed from a continuous marker element and welded to outermost connecting legs [0023].

Claim Rejections - 35 USC § 102

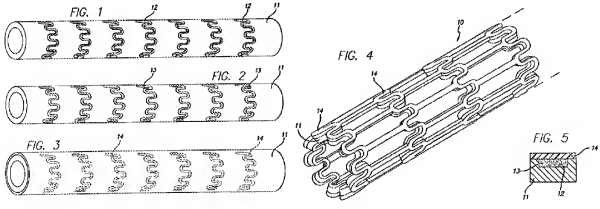
6. Claims 1-3, 6, 9, 11, 12, and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Dang (6,471,721).

The Examiner again notes the presence of product-by-process limitations in applicants' claims. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Please see MPEP 2112 and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The Examiner notes that any article that has the resultant structural limitations despite being formed by a different process will be held to anticipate the claimed article. The limitation regarding the fact that the carrier structure comprises "a cut out metal tube including legs defining a mesh" is a product-by-process limitation because the carrier structure is an intermediate in the final formation of the stent. The fact that the stent has "at least one marker element welded to at least one leg" is a product-by-process limitation in that the resultant article could have marker elements as any number of the legs (see Figure 1 and [0022]). Additionally, the fact that the

comparatively radiopaque material is "filling and completely enclosed by a cover layer" implies that a hollow wire was filled with material; however, if an article is found that comprises a core of comparatively radiopaque material and a cover layer of a metal or metal compound other than the comparatively radiopaque material it will be held to anticipate the claim. Additionally, the limitations of claim 21-23 are also product-by-process limitations.

With regard to claim 2, Dang discloses the device of Figures 1-5.



The stent **10**, which reads on applicants' product-by-process limitations of a "carrier structure comprising a cut out metal tube including legs defining a mesh, and having at least one marker element welded to at least one leg", comprises a radiolucent material, i.e. "difficult to visualize fluoroscopically" (col. 3, lines 22-31 and col. 5, lines 12-23). The stent is produced from a cut out metal tube stock **11** (see Figure 1). The device may have radiopaque material **13**, which reads on applicants' comparatively radiopaque material, incorporated therein (col. 5, lines 38-41). Please note from Figures 1-3 that the radiopaque material is incorporated in cylindrical cut grooves **12** around the circumference of the tube stock (Figure 1-3). The cylindrically cut grooves are then

covered over with the sputtered coating **14**. The tube stock **11**, with the cylindrically cut grooves **12**, filled with radiopaque material **13**, and then covered over with the sputtered coating **14** read on applicants' at least one marker element or core filled wire. The marker elements are attached to the rest of the stent **10** (Figure 4). The radiopaque material **13** is completely enclosed by the tube stock **11** and the sputtered coating **14**, which together (**14** and **11**) read on applicants' cover layer. The material for the tube stock and the sputtered coating include metals and metal alloys (col. 5, lines 14-20 and col. 6, lines 9-11).

Although formed by a different process, i.e. forming grooves **12**, filling with radiopaque material **13** and covering over with the sputtered coating **14**, the cover layer (**14** and **11**) has the same resultant structure as a hollow wire into which the radiopaque material fills the core thereof as claimed.

Additionally, the marker elements being present in the cylindrical sections along with the longitudinal section stretching between each cylindrical section read on the product-by-process limitations of the "radiolucent carrier structure comprising a cut out metal tube including legs defining a mesh, and having at least one marker element welded to at least one leg" of applicants' claim 2. The resultant structure of these product-by-process limitations do not require *all* of the legs defining the mesh to be the radiolucent carrier structure because any of those legs may be cut out and have a marker element welded into the resulting aperture (see e.g. claim 21). The stent of Dang, albeit formed by a different process, and not a "radiolucent carrier structure comprising a cut out metal tube including legs defining a mesh, and having at least one

marker element welded to at least one leg" as claimed, has the same resultant structure, and therefore the device of Dang continues to anticipate the claimed invention.

With regard to claims 21-23, although formed by a different process, the resultant stent has marker elements that read on the marker elements welded into an aperture produced by the removal of a leg of claim 21. The cylindrical parts of the stent that go around the circumference of the stent read on applicants' at least one leg ring formed from a plurality of legs of claim 22 in that each leg in said leg ring may be replaced by a marker element as set forth in claim 23; hence, the resultant structure of Dang reads on claims 22 and 23 because each leg in the leg ring has been replaced by a marker element according to the product-by-process limitations of claim 23. Although the entire cylindrical portions are made of marker elements, applicants' claims 2 and 21-23 do not exclude this.

With regard to claim 1, considering the disclosure at col. 5, lines 14-20 and col. 6, lines 9-11, the Examiner deems that Dang disclose forming both the tube stock **11** and the sputtered coating **14** from nitinol, which is a titanium-nickel alloy. The Examiner provides as a basis for this finding the disclosure at col. 6, lines 9-11, which talks about the sputtered coating **14**, and states "[w]hile one preferred material for the sputtering is 316L stainless steel, other suitable material can be also used." The disclosure at col. 5, lines 14-20 states that the preferred material for the tube stock **11** "is 316L stainless steel, although other materials such as...nitinol...can be used." The Examiner deems

that the "other suitable material" mentioned for the sputtering **14** includes all the alternative materials mentioned for the tube stock **11**, including nitinol.

With regard to claims 3 and 11, the device may be comprised of nitinol, which is a nickel-titanium alloy (col. 3, lines 22-30). The device can be self-expanding as taught by Dang at col. 1, lines 24-26, where they state that the stent may be deployed "automatically by the removal of a restraint."

With regard to claim 6, the Examiner has discussed with regard to claim 2 how the tube stock **11** and the sputtered coating **14**, which together (**14** and **11**) read on applicants' cover layer, and that longitudinal sections of the stent **10** spanning the distance between the cylindrical marker elements are apart of and also read on applicants' carrier structure. The marker element and the carrier structure are formed from the same materials, i.e. parts **14** and **11**. Also the marker elements are clearly attached to the carrier structure by way of parts **14** and **11** and therefore the stent of Dang meets the limitation that the "marker element is attached to the carrier structure at the cover layer."

With regard to claims 9 and 24, the radiopaque material is incorporated as the cylindrical marker elements as seen in Figures 1-4. It is clear from the Figures that the cylindrical marker elements at the two longitudinal ends of the stent **10** are attached to the carrier structure in a region of a longitudinal end of the stent. It is also clear that the marker elements make up the end portion of the stent.

With regard to claim 12, Dang discloses at col. 5, lines 41-44 that the radiopaque material may be gold or platinum.

With regard to claim 20, the Examiner has discussed the structure of the stent with regard to claim 2 above. The stent of Dang is designed to be placed into a patient as that is what stents are designed to do; furthermore, Dang discloses at col. 1, lines 14-27 that stents are particularly adapted to be implanted into a patient's body.

Claim Rejections - 35 USC § 103

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,471,721) as applied to claim 3, in view of applicants' own admissions.

Dang discloses device that may be comprised of nitinol, which is a nickel-titanium alloy (col. 3, lines 22-30) that is inherently a shape memory metal; however, he does not disclose a device that has a design that may allow for temperature dependent change in the configuration of the stent.

Applicants state that it is known to one of ordinary skill in the art to build stents of certain design that allow for temperature dependent change in the configuration of the stent [0026].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to build a stent of a certain design in order to take advantage of this known temperature dependent change in the configuration of the stent. The results would have been predictable; further, the motivation to use this design would be to remove the need for a restraint mechanism or a balloon to expand the stent. This would lead to a product that was cheaper and much more easily deployed.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,471,721) as applied to claim 2, in view of Kranz et al. (6,312,456).

With regard to claim 5, Dang discloses all of the limitations of applicants' claim 2 in section 8 above, and it also discloses at col. 6, lines 56-57 that a biocompatibility layer may be added; however, it fails to disclose that the biocompatibility layer contains silicon carbide.

Kranz et al. disclose at col. 2, lines 51-54 that silicon carbide is used as an outer coating layer on the biocompatible stent and counteracts thrombosis formation; further, at col. 4, lines 27-30 that the silicon carbide is used as an outer covering to avoid stenosis.

Since Dang and Kranz et al. are both drawn to stents, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the silicon carbide outer covering layer of Kranz et al. as the biocompatibility layer of Dang. The motivation for doing so has been stated above and includes *inter alia* counteracting thrombosis formation; further, the overcoating of silicon carbide on the device of Dang would produce a stent that had a multilayered covering layer, and as such would still include the nitinol cover (a metal or metal compound) as well as the additional layer of silicon carbide.

Response to Arguments

9. Applicant's arguments, see Remarks, filed 04/28/2010, the objection to claim 20 and the rejection of claims 1-6, 9, 11, 12, and 20 under 35 USC 112, first paragraph

have been fully considered and are persuasive. The relevant objections/rejections have been withdrawn.

10. Applicant's arguments filed 04/28/2010 have been fully considered but they are not persuasive.

Applicants' argue that the Examiner is improperly treating the struts of Dang as both the legs and the marker elements when they are "two distinctly separate claim elements."

First, the Examiner notes that these limitations are product-by-process limitations because applicants' claims allow for removal of a leg to form an aperture and then filling said aperture with a marker element, i.e. the limitations of "having at least one marker element welded to at least one leg" and the limitations of claim 21. A logical extension of this product-by-process limitation is that each leg in a leg ring may be replaced with a marker element; hence, the stent of Dang with the cylindrical parts of the stent that go around the circumference of the stent made entirely of a marker element reads on applicants' product-by-process limitations in claims 2 and 20-24. It is also noted that applicants' contemplate this embodiment at [0023] of their specification where an entire leg ring is made entirely of a marker element.

The resultant structure of applicants' product-by-process limitations do not require *all* of the legs defining the mesh to be the radiolucent carrier structure because any of those legs may be cut out and have a marker element welded into the resulting aperture (see e.g. claim 21). The stent of Dang, albeit formed by a different process,

and not a "radiolucent carrier structure comprising a cut out metal tube including legs defining a mesh, and having at least one marker element welded to at least one leg" as claimed, has the same resultant structure, and therefore the device of Dang continues to anticipate the claimed invention.

Applicants argue on pages 8 and 10 of their Remarks that "[w]elding is a unique process in metallurgy and leaves a discernable bond," "a weld is a unique bond and a discernable feature," and has cited a chapter of *Mark's Standard Handbook for Mechanical Engineers* to support their position.

First, these statements by applicants do not appear in the reference provided, and therefore these statements by applicants are an opinion that is not necessarily supported by the reference. Second, applicants have not provided this reference in an IDS or in affidavit/declaration form for consideration by the Examiner and/or provided evidence that their article has a "discernable bond."

Applicants are again reminded that "the arguments of counsel cannot take the place of evidence in the record", *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). It is the examiner's position that the arguments provided by the applicant regarding Dang must be supported by a declaration or affidavit. As set forth in MPEP 716.02(g), "the reason for requiring evidence in a declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 24 and 18 U.S.C. 1001". The Examiner has deemed that resultant article of Dang possesses all of the structural limitations of applicants' product-by-process claims. Applicants have not presented any evidence to show that their

resultant article will be structurally different, and therefore applicants have not overcome the Examiner's *prima facie* case.

Applicants argue on page 9 of their Remarks that one of ordinary skill would not confuse the structure of Figure 5 of Dang with a core filled wire as claimed.

Again the Examiner notes that the comparatively radiopaque material "filling" a cover layer to form a "core filled wire" is a product-by-process limitation. The Examiner again respectfully disagrees with applicants' arguments and notes that the ultimate structure of Figure 3 of the current invention and Figure 5 of Dang are not different. Applicants' attention is drawn to their Figure 3 and Figure 5 of Dang.

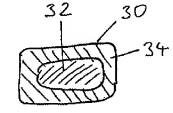
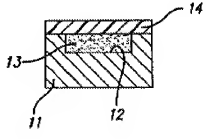


Fig. 3

FIG. 5



Although the tube stock **11** and the sputtered coating **14** are shown to be distinct materials in Figure 5 of Dang, when the coating **14** of Dang is sputtered it will form a *single* material with the tube stock **11** as the two elements are comprised of the *same* material. This means that the tube stock **11** and the sputtered coating **14** will have the *same* ultimate structure as the carrier material **34** of applicants' Figure 3. This means that Figure 5 of Dang will have the *same* resultant structure as applicants' "core filled

wire," and the Examiner notes that applicants' arguments have not overcome this *prima facie* case.

Applicants' argue on page 9 of their Remarks that "[t]he splines of Dang do not alone form a mesh."

The Examiner notes again that the limitations of a "radiolucent carrier structure comprising a cut out metal tube including legs defining a mesh, and having at least one marker element welded to at least one leg" are product-by-process limitations. Applicants' claims allow for removal of a leg to form an aperture and then filling said aperture with a marker element, i.e. the limitation "having at least one marker element welded to at least one leg" and claim 21. A logical extension of this product-by-process limitation is that each leg in a leg ring may be replaced with a marker element; hence, the stent of Dang with the cylindrical parts of the stent that go around the circumference of the stent made entirely of a marker element and the longitudinal splines read on applicants' product-by-process limitations of a "radiolucent carrier structure comprising a cut out metal tube including legs defining a mesh, and having at least one marker element welded to at least one leg" in claim 2. The resultant structure of applicants' product-by-process limitations do not require *all* of the legs defining the mesh to be the radiolucent carrier structure because any of those legs may be cut out and have a marker element welded into the resulting aperture (see e.g. claim 21).

Applicants' argue on page 9 of their Remarks that "the core filled wire is a separate element from the carrier structure."

While the carrier structure may be separate from the marker element in the claims, it is noted that both the carrier structure and the marker element go into forming the stent; hence, the requirements that "radiolucent carrier structure comprising a cut out metal tube including legs defining a mesh" are product-by-process limitations because the carrier structure is an intermediate in forming the final product of the stent. Additionally, the Examiner notes that an aperture may be formed in the carrier structure by cutting out a leg and then welding a marker element into said aperture (see pending claims 21 and Figure 1 and [0022]). Applicants' claims allow for removal of all of the legs in each leg ring and replacing them with marker elements, which would result in the same structure as Dang, albeit by a different process.

Applicants argue on page 10 that the longitudinal sections of Dang would not form "legs defining a mesh" as claimed.

It is again noted that the carrier structure with "legs defining a mesh" and the marker element go into forming the stent, i.e. the resultant product; hence, the requirements that "radiolucent carrier structure comprising a cut out metal tube including legs defining a mesh" are product-by-process limitations because the carrier structure is an intermediate in forming the resultant product of the stent. Applicants' claims allow for removal of a leg to form an aperture and then filling said aperture with a marker element, i.e. the limitation "having at least one marker element welded to at least one leg" and claim 21. A logical extension of this product-by-process limitation is that each leg in a leg ring may be replaced with a marker element; hence, the stent of Dang with the cylindrical parts of the stent that go around the circumference of the stent made

entirely of a marker element and the longitudinal splines read on applicants' product-by-process limitations of a "radiolucent carrier structure comprising a cut out metal tube including legs defining a mesh, and having at least one marker element welded to at least one leg" in claim 2. The resultant structure of applicants' product-by-process limitations do not require *all* of the legs defining the mesh to be the radiolucent carrier structure because any of those legs may be cut out and have a marker element welded into the resulting aperture (see e.g. claim 21).

Applicants argue on page 11 that the independent claims have been amended to recite that the "legs of the carrier structure define the apertures."

This statement is unclear because these limitations are not in the independent claims. The removal of a leg corresponds to an aperture, which then has a leg welded into said aperture, i.e. the limitations of claim 21.

In conclusion, the product-by-process limitations of a "carrier structure comprising a cut out metal tube including legs defining a mesh, and having at least one marker element welded to at least one leg" are met by Dang, albeit by a different process. According to applicants' claims, the carrier structure is an intermediate that does not have any marker element welded to it. The marker element is welded "to at least one leg," wherein this may occur by the product-by-process limitations of claim 21, i.e. "the carrier structure includes at least one aperture produced by cutting out at least one of the legs, and wherein the at least one marker element is welded in the at least one aperture." The resulting structure of Dang, wherein each leg in the leg rings are replaced with a marker element, reads on the structure resulting from the product-by-

process limitations of applicants' claims. Although the entire cylindrical portions are made of marker elements, applicants' claims do not exclude this.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERARD T. HIGGINS whose telephone number is (571)270-3467. The examiner can normally be reached on M-F 10am-8pm est. (Variable one work-at-home day).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Ruthkosky can be reached on 571-272-1291. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Ruthkosky/
Supervisory Patent Examiner, Art Unit 1785

GERARD T. HIGGINS
Examiner
Art Unit 1785

/G. T. H./
Examiner, Art Unit 1785